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09/700,037

07/02/2001

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06/01/2006

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EXAMINER

LANKFORD JR, LEON B

ART UNIT

PAPER NUMBER

1651

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/700,037
Filing Date: July 02, 2001
Appellant(s): TIMMIS ET AL.

Teresa Wiant
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 3/2/2006 appealing from the Office action mailed 6/20/2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

Appeal briefs have been filed in two divisional cases from this application:
10/680676 & 10/680675.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct with the exception that the examiner is hereby withdrawing the prior art rejections in light of appellant's arguments. Appellant has argued that the *raw spectral data* limitation of the claimed invention differs (and unobviously so) from the *image data* used in both prior art references.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

The prior art rejection has been withdrawn so no evidence is being relied upon.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

Art Unit: 1651

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-41 stand finally rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Further, the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's claims were originally drawn to a method of classifying plant embryos according to their "quality." The majority of specification discusses the "quality" of the embryos but also describes how certain "quantifiable characteristics" are indicative of quality, e.g. germination potential and desiccation tolerance. The only real utility that plant embryos (zygotic or somatic) have is to germinate into plants. Any measure of quality or the "quantifiable characteristics thereof" begins and ends with the ability of the embryo to germinate. Any other "quantifiable characteristics" of quality are simply subsets of germination potential, e.g. temperature or moisture tolerance. As such, applicant's claims have always been interpreted by the examiner to be classifying embryos according to at least their ability to germinate into plants.

Appellant has not, in the specification as originally filed, shown possession of the claimed invention nor taught how to make and use said invention. The examiner

understands that the appellant has developed a classification model using the raw data compiled by spectral analysis of embryos of a known quantifiable characteristic.

Appellant has demonstrated that one can take embryos which are visually determined to be good (an old and well known process) , expose the embryos to certain electromagnetic wavelengths (e.g. NIR), collect the raw spectral data produced by said exposure and then take that data and apply well known data processing algorithms to interpret the data and produce a "classification model." It is not in the creation of a such a model that appellant has failed to adequately describe or enable in their claimed invention but in the application of said model. As such, the invention as a whole has not been adequately described or enabled.

The most clear cut way to show possession of an invention is a reduction to practice. Tables 7-11 (and the corresponding sections) in the specification discuss the creation of a classification model and discuss the application thereof however at no point does applicant's specification clearly show that application selected a particular embryo based on their classification model and that said embryo reacted (i.e. germinated) in such a way as predicted by the model. That application and end result would appear to be what applicant's invention requires. Without such a demonstration, there is no reduction to practice.

Absent an actual reduction to practice, appellant can still show possession of an invention but applicant has not done so. MPEP 2163 states: Possession may be shown in many ways. For example, possession may be shown by describing an actual

reduction to practice of the claimed invention. Possession may also be shown by a clear depiction of the invention in detailed drawings or in structural chemical formulas which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention. An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. See, e.g., *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000) (the written description “inquiry is a factual one and must be assessed on a case-by-case basis”); see also *Pfaff v. Wells Electronics, Inc.*, 55 U.S. at 66, 119 S.Ct. at 311, 48 USPQ2d at 1646 (“The word invention’ must refer to a concept that is complete, rather than merely one that is substantially complete.’ “)

Appellant has not described the invention in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention absent any reduction to practice. Appellant’s invention requires that one can assign a “quantifiable characteristic” of quality to an unknown embryo however the specification does not describe that one can actually do that. Appellant has not shown that they possessed a method for properly and practically classifying somatic embryos using spectroscopy.

There appears to be no adequate description for the specific qualities applicant claims in claim 41. The specification appears to be speculative in the ability to use spectral data to classify/select an embryo with any or all of the claimed properties. All

of applicant's data and examples discuss only the correlation between "quality" and morphology there is nothing to convey to one of skill in the art that the properties in claim 41 could be reasonably predicted using a spectral classification model.

It follows logically that the claimed invention has not been enabled by the instant specification because applicant has not taught how to apply the instant invention such that one of skill in the art could predict using applicant's classification model that whether or not any embryo would germinate or have one of the other "characteristics" as in claim 41.

It would require undue experimentation to practice the claimed invention if it could indeed be practiced at all. Appellant's invention requires the spectral analysis of a complex biological entity, the plant embryo. The plant embryo contains multiple membranes and multitudes of complex biological macromolecules along with multitudes of simple molecules. The conifer embryo, for example, contains within its boundaries the genetic material and machinery to transform from its miniscule size into a 100 foot plus tree. One could not make an accurate determination of the chemical composition of an intact plant embryo simply by using spectroscopy because one would expect that the membranes and abundance of chemicals would provide too much interference to accurately trust the results of the data. Appellant is not alleging that they can make such a chemical composition determination but appears to suggest that the spectral data (even though not actually correlated to the presence of a particular

chemical composition) can be trusted to predict the “quality” or “quantifiable characteristics” thereof. One skilled in the art would not expect that any such data could be trusted and used especially in the absence of any working examples.

The specification shows no correlation between “spectral data” and desired characteristics but only between “the spectral data” of one embryo and “the spectral data” of a subsequent embryo.

It would appear that applicant is claiming that if an unknown embryo has the same “spectral data” as the reference embryo then it has the same desired “characteristic”, i.e. the ability to germinate, but applicant has not set forth how a different result is to be classified. Thus applicant has not described or enabled how to classify an embryo. What parameters or data would show that an embryo is of lesser desired characteristic? Greater desired characteristic? There appears to be no indication of how the reference and model are used to classify the desired “characteristic” of an embryo.

(10) Response to Argument

Appellant argues that the examiner’s rejection is in error because the claimed invention does not require a direct comparison of the spectral data of embryos but uses a classification model. The examiner recognizes that the classification model is not a one point direct comparison such as Appellant’s color X analogy, but the instant method does use a direct comparison between two embryos. One embryo (the known)

yields raw spectral data which is applied to an algorithm to yield the classification model and then the model is used to classify the raw spectral data of an unknown embryo. While the comparison is not as simple as "if a plant embryo has color X, then it is likely to germinate," it is still a comparison of the spectral data produced by one embryo to another. Appellant's claimed invention requires a proper classification of an embryo using the classification model developed using another embryo and appellant has not shown that that can be done.

It would appear to require that to demonstrate the possession of the claimed invention, one would have had to taken the raw spectral data of some plant embryos then monitor said embryos to see which could germinate. Germination (or better yet development into a full healthy plant) would be the minimum test for embryo quality. Upon germination, one could then look back at the spectral data and properly classify the data from the germinated embryos as the data of a "quality embryo." At this point, a classification model could properly be constructed. Next the model would need to be tested and in doing so, one would take the raw spectral data of some unknown embryos. One would then select embryos which should have high quality according to the model and test them to see if they do in fact germinate. Controls should of course be run. One would need to see if the embryos predicted by the model to germinate would in fact germinate to know if the model is in fact accurate.


Appellant points to the specification to show data is collected and analyzed but no where in the specification is there description of a reduction to practice or working

example using spectral data to accurately predict the quality of an unknown embryo which is what the claims require.

At the time the invention, Appellant had in their possession the ability to measure the spectral absorption, transmittance and reflectance of a plant embryo, and manipulate the data produced using a variety of data processing algorithms, however Appellant did not show possession of (nor enable) a method for effectively classifying unknown plant embryos using this processed spectral data.

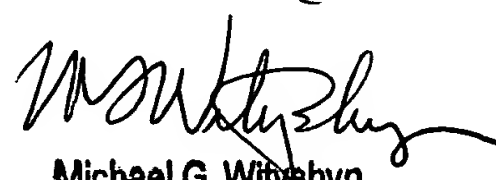
For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



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